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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/692,634	10/19/2000	Paul John Rennie	8308	8314

27752 7590 12/17/2002

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 12/17/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/692,634

Applicant(s)

RENNIE ET AL.

Examiner

Shahnam Sharareh

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 20-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 20-30 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Amendment filed on September 26, 2002 has been entered. Claims 1-9, 20-30 are pending and are under consideration. Any rejection that is not addressed in this Office Action is considered obviated in view Applicant's arguments and amendments.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. Claims 1-9, 20-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's arguments with respect to this rejection, filed on September 26, 2002, have been fully considered but they are not persuasive.

Applicant argues that the specification is adequately enabled and that Applicant does not require clinical data for an assessment of the claimed composition instantly recited.

In response, Examiner states that instant rejection is based on 112 1st paragraph analysis as reasoned in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400, 1404, Fed. Cir. 1988. Having the factors set forth in *In re Wands*, Examiner states that the specification neither enables one of ordinary skill in the art how to practice methods to "prevent" cold and influenza viruses (as claimed in the instant method claims 9-8, 28-30), nor does it

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adequately enable for a composition for prevention of cold and influenza. At best the claimed invention is enabling for treatment or prophylactic treatment of such conditions.

As set forth in the previous office action, "preventing a disease" or "methods of preventing a condition" are directed to an absolute clinical outcome, meaning, that such condition would not occur in the recipient, when such therapy is employed. Having such interpretation and the scope of the instant claims, Examiner states that the instant specification does not meet the requirements set forth by Wands factors. Namely, (a) the state of the prior art concerning methods of preventing a disease condition requires adequate assessment of patient disposition, identification, screening, and monitoring the clinical outcome in given time intervals; (b) there is no correlation between the working example describing an in the instant specification and method of preventing pathological conditions such as cold and influenza viruses; (c) the amount of guidance presented in the specification fails to present a required amount of guidance to perform the claimed method without undue experimentation. Accordingly, undue experimentation is necessary to practice the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 103

3. Claims 1-9, 20-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davidson et al US Patent 6,080,783 in view of Szentmiklosi and Gangadharan et al US Patent 5,643,582

Applicant's arguments with respect to this rejection have been fully considered but they are not persuasive. Applicant argues that none of the references teach the

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combination of pyroglutamic acid and organic acid having a dissociation constant of 3.0 to about 5.0

First, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Accordingly, the rejection is based on the combined teachings of the references, and the combined teachings of the references provide for all elements of the instant claims.

Second, contrary to Applicant's contention, Gandahara et al clearly teach for the use of pyroglutamic acid (col 4, lines 45-48), and a suitable organic acid such as benzoic acid (col 5, lines 26-31). As these acids are the same as instantly claimed, their pKa is the same. Further, the cited references are directed to aqueous solutions, subsequently, pyroglutamic acid salts when in an aqueous solution exist in their acidic form. In fact, Szentmiklosi specifically recognizes pyroglutamic acid and salts thereof as being substantially art equivalent as they are interchangeably used in topical formulations (see abstract and examples 1-5 of the patent).

Further, the instant claims are directed to nasal compositions comprising an effective amount of pyroglutamic acid, an effective amount of metal salts, a suitable carrier and methods of treating cold and influenza viruses. All cited references are directed to such utility and teach the elemental components of the instant claims.

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Davidson provides for nasal compositions comprising zinc metal, a thickener, and other suitable carrier ingredients for treatment of cold. (see abstract, examples 1-6). Davidson's compositions do not contain pyroglutamic acid. Szentimiklosi discloses L-pyroglutamic acid or salts thereof in therapeutic topical preparations (see abstract, example 9). Szentimiklosi's compositions contain suitable topical ingredients such as an organic acid, a mucoadhesive agent and even a propellant (examples 2-9). Szentimiklosi does not teach nasal formulations of his compositions. Gangadharan discloses suitable compositions for nasal application comprising a humectants such as 2-pyrrolidinone-5-carboxylic acid (same as instant pyroglutamic acid), a moisturizing agent, a polymeric bioadhesive agent, ascorbyl palmitate, benzoic acid, and a pH modifier a carboxylic acid, a therapeutic agent and a pH modifying agent (see abstract, col 2, lines 50-67; col 4, lines 5-65; col 5, lines 20-30, 33-60; col 6, lines 6-56; col 10, line 50; col 13-14). Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to combine their teachings as set forth in previous Office Action to reach at the instant claims.

Finally, absence of showing a criticality and unexpected results, optimizing viscosity and pH values of a topical composition would not impart patentability, because such modifications can be obtained by routine experimentations.

Conclusion

No claims are allowed. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.